

SPECIAL 510(k): Device Modification  
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K042070

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This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.) – Hepcon Hemostasis Management System (HMS) Heparin Dose Response (HDR) Cartridge - #K894317.
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use). – The submitter provided this information on pp. 2 – 3 of the submission.
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.  
**This change was for** replacement of USP bovine heparin with USP porcine heparin. The bovine heparin is no longer commercially available for manufacture and clinical use.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and product stability. A comparison chart is provided in Table 1 on p. 3 of the submission.
5. A **Design Control Activities Summary** which includes:
  - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis. This information is found in Appendix C. The manufacturer supplied Failure Mode and Effects Analysis (FMEA) based upon these documents:
    - PC1.48 – Product/Process Risk Management Procedure
    - ISO 14971 – Medical Devices – Application of Risk Management to Medical Devices
    - 21 CFR Part 820 – Quality Systems Regulations
    - 98/79EC – In vitro Diagnostic Device Directive – Council Directive
    - AP5496 – Product Structure, HMS HDR
  - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied. This information is found in Appendix D.
    - Testing included porcine cartridge channel pair precision/stability; within-lot (between-cartridge) and between-lot precision; comparison of bovine HDR and porcine HDR cartridges vs the HR-ACT cartridges on the HMS Plus; and comparison of (3) lots of HDR cartridges vs HR-ACT on the HMS. The acceptance criteria were identified and met.

- c) A declaration of conformity with design controls. The declaration of conformity should include:
  - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
  - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
 This information is supplied in Appendix G.

**6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).** These documents are supplied in Appendixes H, F and E, respectively.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

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|          | (Reviewer's Signature) | (Date) |
| Comments |                        |        |
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revised:8/1/03